



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0020] (formerly Docket No. 2007D-0249)

Guidance for Industry: Preparation of Investigational Device Exemptions and Investigational New Drug Applications for Products Intended to Repair or Replace Knee Cartilage; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Preparation of IDEs and INDs for Products Intended to Repair or Replace Knee Cartilage" dated December 2011. The guidance document provides sponsors of an investigational device exemption application (IDE) or an investigational new drug application (IND) recommendations about certain information that should be included in a submission describing a product intended to repair or replace knee cartilage. The guidance does not apply to prostheses such as unicondylar or total knee implants, or meniscus replacement products. The guidance supplements recommendations regarding IDE and IND submissions contained in other FDA publications. The guidance announced in this notice finalizes the draft guidance of the same title dated July 2007.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448; or the Division of Small Manufacturers, International, and Consumer

Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800; or by calling CDRH at 1-800-638-2041 or by faxing a request to CDRH at 301-847-8149. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Lori Jo Churchyard,
Center for Biologics Evaluation and Research (HFM-17),
Food and Drug Administration,
1401 Rockville Pike, suite 200N,
Rockville, MD 20852-1448,
301-827-6210;
or
Elizabeth L. Frank,
Center for Devices and Radiological Health,
10903 New Hampshire Ave.,
Bldg. 66, rm. 1407,
Silver Spring, MD 20993,
301-796-5650.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry: Preparation of IDEs and INDs for Products Intended to Repair or Replace Knee Cartilage" dated December 2011. The guidance document provides sponsors of an IDE or an IND recommendations about certain information that should be included in a submission describing a product intended to repair or replace knee cartilage. The guidance does not apply to prostheses such as unicondylar or total knee implants, or meniscus replacement products. Human cells, tissues, and cellular and tissue-based products (HCT/P's) regulated solely under section 361 of the Public Health Service Act (42 U.S.C. 264) and 21 CFR part 1271 are beyond the scope of this guidance. A product intended to repair or replace knee cartilage may include a biologic, device, or combination product (comprised of two or more different types of regulated constituents) whose components would individually be regulated by CBER and CDRH. The guidance addresses issues that may arise in the development of articular cartilage repair or replacement products. The guidance supplements other FDA publications on IDEs and INDs that may be relevant to development of these products.

In the Federal Register of July 9, 2007 (72 FR 37245), FDA announced the availability of the draft guidance of the same title dated July 2007. FDA received numerous comments on the draft guidance, and those comments were considered as the guidance was finalized. In response to comments, changes incorporated in the guidance included adding new sections and clinical study schedules, elaborating on nonclinical data considerations, and updating the references. In addition, organizational and editorial changes were made to improve clarity. Some terminology was changed to harmonize terminology within the Agency and does not change the intent of the

guidance. The guidance also reflects input received from the public and the Cellular, Tissue, and Gene Therapy Advisory Committee meeting held on May 15, 2009. The guidance announced in this notice finalizes the draft guidance dated July 2007.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014; and the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078.

III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either:

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>,

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>, or <http://www.regulations.gov>.

Dated: January 11, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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